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VIA ECF (FILED UNDER SEAL)

Honorable Tonianne J. Bongiovanni, U.S.M.J.
United States District Court
District of New Jersey
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street
Trenton, New Jersey 08608

Re: *Arbutus Pharma Corp., et al. v. Pfizer Inc., et al.*
Civil Action No. 23-1876 (ZNQ) (TJB)

Dear Judge Bongiovanni:

This firm and Paul Hastings LLP represent Defendant BioNTech SE in the above-referenced action. We respectfully provide, jointly with Pfizer Inc. ("Pfizer"), Defendants' opposition to Plaintiffs' motion to compel discovery that was submitted to the Court on May 29, 2024 ("Motion"). Plaintiffs filed the Motion amidst ongoing meet and confer correspondence between the parties. As Defendants informed the Court at the status conference on June 5, 2024, Defendants sent Plaintiffs a responsive letter on June 3, 2024 (Ex. 1 ("Defendants' Letter")), which followed and responded to the Motion and Plaintiffs' prior letter dated May 20, 2024 (Ex. 2). Defendants' Letter continued the parties' meet and confer efforts and included compromise proposals aimed at resolving the parties' disputes without requiring the Court's intervention. The issues raised in the Motion are not ripe for the Court's consideration. Because Plaintiffs proceeded to file the Motion without waiting for Defendants' responses and in contravention of the requirement for a letter seeking leave to file such a motion, Lite, N.J. Federal Practice Rules at 804 (Gann, 2024), we provide our opposition herewith.

For the reasons set forth below, Defendants respectfully request denial of Plaintiffs' Motion in its entirety. Defendants continue to stand by and honor their compromise proposals.

1. Physical Samples

A. RFP No. 90 Regarding Samples of the Accused Product

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

1 [redacted]

[redacted]

B. RFP No. 91 Regarding Raw Ingredients

The "Accused Product" as defined in the Complaint is the COVID-19 vaccine itself, not all of its individual components as they may exist independent of the vaccine. *See* ECF No. 1 at ¶ 8.[2] Nonetheless, Plaintiffs move this Court to compel production of raw ingredients used in production of the vaccine. Specifically, they want a 10 gram sample of each ingredient divided into 5 gram aliquots. [redacted]

[redacted]

[2] "This is a civil action by Plaintiffs against Defendants under the patent laws of the United States, 35 U.S.C. § 101 *et seq*., seeking damages for Defendants' infringing manufacture, use, sale, offer for sale, and/or importation of their COVID-19 vaccine and any COVID-19 mRNA-LNP vaccine products, including: pediatric doses; booster doses; supplemental doses; reformulations; boosters or re-vaccinations; variant-specific formulations; bivalent formulations; and the products known or marketed as Pfizer-BioNTech SE (BioNTech) COVID-19 vaccine, Comirnaty, Tozinameran, BNT162b2, or PF-07302048 (collectively, the 'Accused Product' or 'Defendants' vaccine')."

[3] [redacted]

2. Production of Noncustodial Data

Plaintiffs ask this Court to mandate a form of document review that requires BioNTech to manually search all of its extensive electronic, noncustodial data sources or, in the alternative, require BioNTech to run all ***forty-two*** previously proposed search terms across the noncustodial data sources. (Motion at 3-4.) As shown below, this request is unreasonable, overly broad and unduly burdensome, and unsupported by case authority. BioNTech's procedures for document review and production are reasonable and permissible under Fed. R. Civ. P. 26 and 34, and are consistent with the parties' ESI Order. (*See* ECF No. 56.) Even though Plaintiffs are wrong, BioNTech offered a reasonable compromise proposal to resolve this issue and avoid further disputation. The Motion should be denied.

a. Manual Searches for Noncustodial Data are Unreasonable and Not Supported by Case Law

The first aspect of Plaintiffs' request, requiring BioNTech to conduct manual searches of its noncustodial data, is unreasonable and contrary to the authority in this district. Indeed, Plaintiffs have not identified any authority requiring such manual searches. (*See* Ex. 1 at 3.) Absent any supporting authority, Plaintiffs' only basis for demanding that Defendants manually search their noncustodial data is simply that Plaintiffs say in conclusory fashion [redacted] (Motion at 3.) To be clear, Plaintiffs' alleged search methodology (and their description thereof) was not mandated by the ESI Order in this case (ECF No. 56), nor requested by Defendants. Whether Plaintiffs' approach is sufficient will remain to be seen by their productions as discovery continues.[4] In any event, Plaintiffs' alleged search procedures, and their assumptions about Defendants' data sources, do not establish any standard or requirement. Instead, the standard in this district is to allow a party to reasonably determine its search methodologies, which is reasonable given that no two parties are assumed to have the same document repositories, data servers, or management systems. *See Lifescan, Inc. v. Smith*, No. 17-5552, 2022 WL 20853087, at *10-11 (D.N.J. July 29, 2022) ("[C]ourts normally play no role in the search design, search tools, search terms or designation of custodians unless the choices of those items are 'manifestly unreasonable,' or the requesting party 'demonstrates that the resulting production is deficient'.").

Defendants' proposed search parameters satisfy this standard and are reasonable and consistent with the ESI Order. The ESI Order allows the use of "reasonably tailored search terms to locate potentially responsive ESI" generally (*i.e.*, without differentiating between custodial and

4 [redacted].

noncustodial data) indicating search terms are appropriate and contemplated for use with noncustodial data. (ECF No. 56 at 5.) As Plaintiffs acknowledge, BioNTech has identified the noncustodial data sources that are most likely to contain non-duplicative discoverable information, and BioNTech has further proposed that search terms be run against noncustodial documents to identify materials for review. (*See* Motion at 3.) Defendants' methodology, therefore, is consistent with the case law and the ESI Order. *MSP Recovery Claims, Series, LLC v. Sanofi-Aventis U.S. LLC*, 2:18-cv-2211, 2022 WL 20359241, at *13 (D.N.J. Feb. 8, 2022) (approving document search methodology wherein "custodial and non-custodial databases are culled using search terms"). Plaintiffs have not articulated any legitimate reason to assert that Defendants' method is inadequate. Although Plaintiffs' Motion takes issue with BioNTech's proposed search terms, that is typically a matter for discussion among the parties. The proposal—discussed below—for Plaintiffs to identify ten (and potentially a reasonable number more) additional search terms more than resolves Plaintiffs' supposed concern with search terms. (*See* Ex. 1 at 2.)

Moreover, aspersions cast by Plaintiffs concerning Defendants' document production to date are unfounded. Defendants have already produced the BLA, Emergency Use Application ("EUA"), and Investigational New Drug Application ("IND") submitted to the FDA and related communications with the FDA for the Accused Product, Comirnaty®, as Plaintiffs acknowledge. (Motion at 3.) Defendants' production to date includes more than 1.8 million pages, and the BLA and other regulatory documents are extensive and include, as required, detailed explanations and information regarding the structure, manufacturing, and marketing of Comirnaty®. Thus, any suggestion by Plaintiffs that Defendants' production has been minimal (referring to these as the "only" noncustodial documents produced to date, (Motion at 3)) is unfounded.

In addition, BioNTech has diligently collected custodial documents and is prepared to review and produce non-privileged, responsive materials, but Plaintiffs have held up this effort by failing and/or refusing to reach agreement on a reasonable set of search terms within the parameters of the ESI Order for such custodial documents, including having improperly proposed ***forty-two*** additional search terms for custodial documents (discussed further below). Plaintiffs subsequently acknowledged that search terms for custodial documents are limited to ten (as their Motion now also confirms, *see* Motion at 4 n.4), yet they have done nothing to bring their proposal into compliance with this limit.

b. Search Terms

The second alternative aspect of Plaintiffs' request, that ***forty-two*** additional search terms be run against BioNTech's noncustodial data, is unreasonable and unduly burdensome. Plaintiffs contend that BioNTech argued that the ESI Order limits the number of search terms for noncustodial data to ten. (Motion at 4.) That is inaccurate. In fact, BioNTech objected to Plaintiffs' proposal of forty-two additional terms to their ***custodial*** data, which would violate the ESI Order's restriction on the number of these terms to ten (a point Plaintiffs' Motion now acknowledges, as discussed above). (Ex. 8 at 2-3 (April 12, 2024 Email from S. Kung).)

BioNTech's actual argument relevant to this Motion is simply that applying these ***forty-two*** terms to their ***noncustodial*** data is not "reasonably tailored," as required by the ESI Order. Plaintiffs notably ignore BioNTech's explanations as to why these terms are unworkable. (*Id.* at 2 (noting the ESI Order's prohibition against "over-broad terms (*e.g.*, product and company names)").) Plaintiffs' Motion also makes no effort to explain how the proposed ***forty-two*** additional terms are "reasonably tailored."[5] Many of the terms, for example, are combinations of the product name and commonly used scientific terms, while many others are extensive strings of numerous disjunctive terms encompassing an expansive scope [redacted]. Such terms are not reasonably tailored because they would cover a wide swath of documents that are unrelated to the issues in this case. The Motion should be denied on this independent basis alone.

Nevertheless, BioNTech has gone further and offered a reasonable resolution: after Plaintiffs filed their Motion, BioNTech offered a compromise of ***ten*** additional terms to their noncustodial data—consistent with the ten additional terms permitted by the ESI Order to custodial data—as well as a reasonable number of ***additional***, "reasonably tailored" terms if Plaintiffs believe they are necessary and can support the request with explanations of relevance and proportionality. (Ex. 1 at 2.) This reasonable proposal should resolve the parties' dispute, but Plaintiffs did not respond. The Motion should be denied.[6]

3. Noncustodial R&D Documents Concerning the Purported Entire Accused Product

Plaintiffs request research and development documents concerning ***all*** components of Comirnaty®. (Motion at 4 (seeking "research and development documents concerning the entire Accused Product," including "the messenger RNA ("mRNA") component and all other components").) This request is overly broad and not proportional to the needs of this case because the Asserted Patents are all directed to compositions of lipids, and the aspects of Comirnaty® that are alleged to infringe the Asserted Patents are the lipid nanoparticle ("LNP") components, which constitute only a portion of the Accused Product. Plaintiffs' requests covering ***all*** components of

[5] Plaintiffs' argument that "if BioNTech truly has no such documents, then running Plaintiffs' requested search terms should be easy and noncontroversial," Motion at 4, is incorrect. Defendants have not argued that they do not have any such documents; rather, they have argued that the ***forty-two*** search terms are overly broad and not "narrowly tailored" (and that production of manufacturing documents is cumulative of Pfizer's production as the manufacturer of the product that is sold in the United States).

[6] Since Plaintiffs filed the present motion to compel, Plaintiffs agreed with Pfizer on Pfizer's search terms and agreed that Pfizer will search non-custodial data sources for manufacturing documents without using keywords. Defendants believe that Plaintiffs' Motion as to this issue is moot with respect to Plaintiffs and Pfizer.

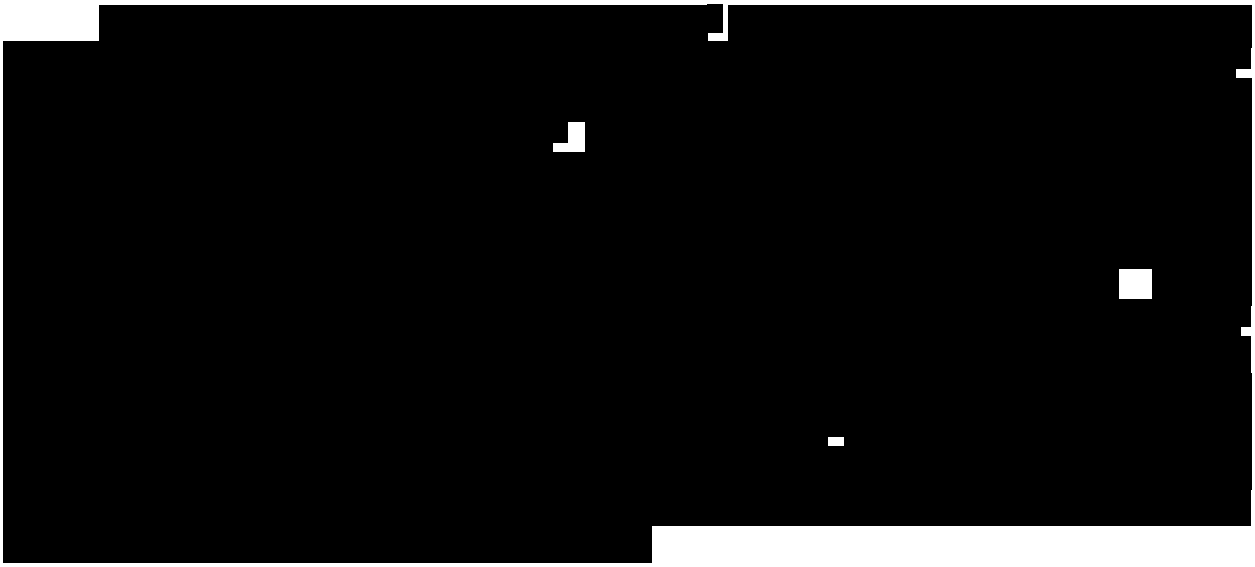
the Accused Product is an overbroad fishing expedition into the records of BioNTech for irrelevant information. [redacted] This scope of response and production by Defendants is reasonable and appropriate given the claims and defenses at issue in this case.

BioNTech has engaged in mRNA research for decades. Plaintiffs have offered no legitimate justification for seeking all research and development documents irrespective of whether they relate to the LNP components. Plaintiffs emphasize each patent's generic reference to mRNA, and each patent claim's recitation of "an RNA or nucleic acid," arguing that these are "enough to warrant discovery of research and development documents concerning the entire Accused Product." (Motion at 5.) But there is no dispute that "mRNA" is in the Accused Product. This incantation of a word fails to justify discovery of ***all*** research and development for Comirnaty®, as, again, the patents focus on alleged LNPs, which Plaintiffs in fact tout as the focus of their company. Indeed, none of the asserted patents discuss virus sequences or modified mRNA, yet those are substantial research and development subjects encompassed in Plaintiffs' request. Plaintiffs have failed and/or refused to show how extensive discovery into research and development far beyond the LNP components of Comirnaty® is relevant to any issue of infringement or the purported validity of Plaintiffs' patents. *See Cambria Co. LLC v. Hirsch Glass Corp.*, No. 21-10092, 2023 WL 4267598, at *4 (D.N.J. June 29, 2023) (denying discovery where "[n]o claim, limitation, specification, or embodiment of the asserted design or utility patents has anything to do with" the requested information). The Motion should be denied on this basis.

Nevertheless, BioNTech has offered to go further than indicated in their initial objections and responses, specifically agreeing to produce documents sufficient to show an overview of the development of the components of Comirnaty®, including components other than the LNP. (Ex. 1 at 3.) Plaintiffs have not responded to this offer. BioNTech's proposal covers sufficient information regarding the research and development of the non-LNP components (which will also confirm that this research and development regarding non-LNP components has nothing to do with the issues in this case), without unduly burdening Defendants to produce every single document concerning their companies' RNA research. The Motion should thus be denied on the independent basis that BioNTech has offered a reasonable compromise to resolve the dispute.

4. Manufacturing of Comirnaty®

Plaintiffs' Motion challenges the adequacy of Defendants' production of manufacturing documents, (Motion at 5-6), [redacted]



In view of the above, Plaintiffs' Motion as to this topic should be denied as moot.

5. Documents Produced by Defendants in the *Alnylam* Litigation

Plaintiffs' Motion seeks to require Defendants to produce every document produced or served in a different litigation, *Alnylam Pharmaceuticals, Inc. v. Pfizer Inc., et al.*, No. 22-cv-336-CFC (D. Del.) ("*Alnylam*"), in which a company unrelated to the parties in this case (Alnylam) is asserting its own patents that are unrelated to the patents in this case. Plaintiffs' request is overbroad, designed to burden Defendants, and not proportional to the needs of this case.

First, as noted above, the *Alnylam* case involves different and unrelated patents that are owned by an entirely different company. The only thing the cases have in common is the same Accused Product, Comirnaty®, as to which Plaintiffs are already obtaining discovery in this case. The *Alnylam* litigation is focused on the purported invention of a specific ingredient made by a third party (Acuitas) and used by BioNTech in Comirnaty® (called "ALC-0315"). Plaintiffs are not asserting in this case patents purporting to relate to the discovery of a new lipid ingredient. The patents at issue in the *Alnylam* case have different inventors, different priority dates, and cover different aspects of technology than the patents at issue here. Plaintiffs' request for wholesale production of every document produced or served in that case is unwarranted and overbroad, as it would encompass and involve production of irrelevant documents disproportionate to the needs of

[7] Plaintiffs' Motion notably does not even specifically request BioNTech's independent production of these manufacturing documents Pfizer will produce, nor challenge BioNTech's position that such an additional search and production would be unjustified.

the case (or else impose the substantial and disproportionate burden of re-reviewing all documents produced in *Alnylam* for relevance here).

Courts have consistently denied fishing discovery requests into other cases involving different patents, merely because they involve aspects of the same accused products.[8] *See, e.g.*, *Depomed, Inc. v. Purdue Pharma L.P.*, No. 13-571, 2016 WL 6089699, at *4 (D.N.J. Oct. 14, 2016) (affirming denial of motion to compel documents from another litigation that involved different patents and concerned different infringement and invention issues); *Vasudevan Software, Inc. v. MicroStrategy Inc.*, No. 11-cv-06637, 2013 WL 597655, at *2-4 (N.D. Cal. Feb. 15, 2013) (denying motion to compel documents from past litigations involving the same accused products but different patents).

Plaintiffs argue that the requested discovery is justified because *Alnylam* involves "the *same accused product* and the *same claimed subject matter*," (Motion at 6), but this assertion—particularly the "*same claimed subject matter*"—is unsupported by the Motion and wrong. First, the *Alnylam* litigation relates primarily to a specific cationic lipid, whereas this case relates generally to the lipid components in a formulation. Moreover, for this assertion of supposedly "*same claimed subject matter*," Plaintiffs only highlight a single excerpt of a claim from just one of the six patents asserted in *Alnylam* (U.S. Patent 11,382,979), comparing it to a single excerpt of a claim from U.S. Patent No. 8,492,359 asserted in this case, both excerpts referring to the molarity of cationic lipids. But patents are not about one excerpt from a claim. The remaining portions of the claim from U.S. Patent 11,382,979 deal with the specific chemistry of the claimed lipid and do not overlap at all with the claims at issue here. The remainder of the cited claim from the *Alnylam* patent recites the following limitations, none of which are remotely close to overlapping with what is recited in the Asserted Claims here:

> the cationic lipid comprises a head group, two hydrophobic tails, and a central moiety to which the head group and the two hydrophobic tails are directly bonded, wherein
>
> (a) the central moiety is a central carbon or nitrogen atom;
>
> (b) each hydrophobic tail independently has the formula -(hydrophobic chain)-(ester group)-(hydrophobic chain), wherein the ester group is —OC(O)— or —C(O)O—; and

[8] Plaintiffs' assertion that courts have compelled otherwise is misleading. In the only case that Plaintiffs cite, the Court granted discovery because the opposing party made no effort to explain why the request was "outside the scope of discoverable material for the present case and has therefore failed to meet its burden in opposition." *Alloc, Inc. v. Unilin Beheer B.V.*, 2006 WL 757871, at *5 (E.D. Wis. Mar. 24, 2006). This case does not reflect a general standard that documents produced in other cases concerning the same accused products are discoverable.

(c) for at least one hydrophobic tail,

(I) the terminal hydrophobic chain in the hydrophobic tail is a branched alkyl, where the branching occurs at the α-position relative to the ester group;

(II) the hydrophobic tail has the formula —R12-M1-R13, wherein R12 is a C4-C14 alkylene or C4-C14 alkenylene, M1 is the ester group, and R13 is a branched C10-C20 alkyl;

(III) the total carbon atom content of the tail —R12-M1-R13 is 21 to 26; and

(IV) the ester group is separated from a terminus of the hydrophobic tail by from 6 to 12 carbon atoms.

Moreover, any claim element in any patent is also subject to interpretation based on those patents. Thus, the overlapping subject matter that Plaintiffs stretch to identify is in fact narrow, in addition to the fact that Plaintiffs only cite ***one of the asserted patents*** in *Alnylam*.

The differences between the asserted patents and subject matter in the cases undermine all of Plaintiffs' arguments, as the documents produced and served in *Alnylam*, whether related to infringement or damages, will necessarily include substantial documents related solely to the non-overlapping aspects of the *Alnylam* patents. Plaintiffs' conclusory assertion that these documents have "clear relevance," (Motion at 6), is thus unsupported and false, and the suggestion that Defendants will incur no burden because they must only produce what they already produced in *Alnylam* (and not review any new documents) is misguided as well, because such wholesale production would mean producing substantial volumes of irrelevant, undiscoverable material. The alternative is for Defendants to review those productions to identify and remove the irrelevant material, an incredibly burdensome task that would be especially wasteful given that Defendants are otherwise already producing the actually relevant documents. And, in any event, even if the documents would be produced wholesale (ignoring the broad swaths of irrelevant materials that would entail), Defendants would need to review these documents at least to verify or reconcile confidentiality designations under different Protective Orders, and send notices to third parties on reproducing their documents in this case, so there would still be substantial burden. For all of the above reasons, Plaintiffs' request for the *Alnylam* documents should be denied.

Defendants thank Your Honor for considering the aforementioned points and respectfully request denial of Plaintiffs' motion.

Respectfully submitted,

s/ William P. Deni, Jr.
William P. Deni, Jr.

cc: All counsel of record (via ECF)